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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,801	08/10/2000	Jennifer L. Mitcham	210121.462C4	6804

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EXAMINER
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ZEMAN, MARY K

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/636,801

Applicant(s)

MITCHAM ET AL.

Examiner

Mary K. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 73-81 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 73 is/are allowed.  
6) ☒ Claim(s) 74-81 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 73-81 are pending in this application.

Applicant's arguments filed 4/28/06 have been fully considered but they are not completely persuasive. Any rejections not repeated below have been withdrawn.

Claim 73 remains allowed.

With regard to the rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is withdrawn.

Applicant argues that the specification, as filed, provides adequate guidance to identify and create the genus of polypeptides set forth in the claims. Applicant argues that the disclosure to general cloning and purification techniques, and the specific experiments for cloning O8E (SEQ ID NO: 392) provide basis for the broad genus of peptides having 90% identity to SEQ ID NO: 392. Applicant argues that the combination of the sequence identity with the requirement for a) overexpression in ovarian cancer tissues or b) reactivity with an antibody which binds to SEQ ID NO: 392 provides one of skill in the art a starting structure and functional test such that identifying variants within the scope would not be undue experimentation.

Claims 74-81 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification, as filed, fails to provide basis for the genus of polypeptides being claims in claims 74-81. The genus includes polypeptides having varying levels of identity to SEQ ID NO: 392, as well as polypeptides comprising merely a small part of SEQ ID NO: 392 (amino acids 1-27) and peptides having varying levels of identity to the SEQ ID NO: 392 that react with an antibody which binds to SEQ ID NO: 392. The specification does not provide basis for this genus of polypeptides.

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Applicant argues that the specification provides ample guidance for one of skill in the art to obtain polypeptides falling within the claimed genus of polypeptides. Applicant argues that the binding specificity test and the overexpression test provide the requisite functionality in combination with the base structure of SEQ ID NO: 392. This is not completely persuasive. The specification does not provide for peptides comprising only amino acids 1-27 of SEQ ID NO: 27. the specification does not provide for polypeptides having deletions or insertions which may radically affect immunogenicity yet still meet the 90% requirement. The specification does not identify what the antigenic sites of this sequence are such that one of skill in the art would reasonably predict which sequences could be altered, yet retain immunogenicity. The identification of antigenicity is not entirely predictable nor is it clear that any particular predicted antigenic site would bind to an antibody raised against the entire sequence.

The specification provides a set of 20-mer peptides of O8E, however it is not clear if SEQ ID NO: 392 was used to generate these polypeptides. The specification does not provide a polypeptide comprising residues 1-27 of SEQ ID NO; 392 and which reacts with an antibody which specifically binds to SEQ ID NO 392. The specification does not provide a polypeptide comprising residues 1-27 of SEQ ID NO 392 and is overexpressed in ovarian cancer. The specification does not provide polypeptides which have the binding specificity and the recited sequence similarity.

Claims 76-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendments to claims 76 and 77 are new matter. The specification does not provide a polypeptide comprising residues 1-27 of SEQ ID NO; 392 and which reacts with an antibody which specifically binds to SEQ ID NO 392. The specification does not provide a polypeptide comprising residues 1-27 of SEQ ID NO 392 and is overexpressed in ovarian cancer. The specification does not provide polypeptides which have the binding specificity and the recited sequence similarity.

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The pages of the specification (pages 16 and 17) to which Applicant points for basis do not support these specific limitations.

### ***Conclusion***

Claims 73 is are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272 0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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MARY K. ZEMAN  
PRIMARY EXAMINER  
